COMMISSIONER-DESIGNATE MIMICA'S HEARING IN THE EP

DEFENSIVES

1. REVISION OF THE MEDICAL DEVICES LEGISLATION

1.1. Would a pre-market approval system be necessary for some categories of high risk medical devices?

- The proposal does not foresee a pre-market authorisation system for medical devices through a regulatory authority. Such regulatory shift would be detrimental to innovation and to the competitiveness of the European medical device sector, without any demonstrated added value for patient safety.

- Pre-market authorisation would also lead to higher costs[1] and inappropriate delays[2], which ultimately would hinder patients' access to innovative medical devices. Recent studies have shown that devices have been available in Europe much earlier before being made available in the U.S where a pre-market authorisation system is in place (*e.g.* transcatheter aortic valves), without difference in terms of patient safety.

- Moreover, a pre-market authorisation system in Europe would not be feasible with available resources. What is needed is the right balance between pre-market controls and post market controls.

- Let's not forget that the PIP case is a case of wrongdoing by an individual manufacturer. The safety issue was not related to a problem of authorisation. A pre-market authorisation system would not have prevented the manufacturer's fraud. However, it could have been detected much earlier with more effective controls after approval, as foreseen by the proposal.

1.2. Is the scrutiny procedure sufficient for high risk medical devices?

- A 'revolution' in the system of conformity assessment is not necessary.

- What is needed is rather a substantial 'evolution'. This means, on the one hand, reinforcing the designation and monitoring of notified bodies and, on the other, strengthening the quality and depth of the conformity assessment they perform (in particular in the clinical evaluation).

- This is why the proposal introduces the obligation for notified bodies to notify new applications for conformity assessment of high-risk devices to a committee of experts appointed by the Member States. This scrutiny procedure is important since it empowers the public authorities to have a 'second look' at individual assessments and give their views before the device is placed on the market.

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1 Placing a device on the market amount to a max of 30.000EUR while a central pre-market authorisation for a medicinal product is up to 250.000EUR plus additional costs

2 A medical device is placed on the market in (on average) 3 months (extended by 2 months by the scrutiny mechanism contained in the proposal) while a central pre-market authorisation of a medicinal product requires in average 14 months.

1.3. Why do you object to a pre-market approval for medical devices

- The option to transfer the responsibility for the assessment of the safety and performance of medical devices from notified bodies to a regulatory authority and to replace the CE marking by a marketing authorisation, such as exists in the field of pharmaceuticals, was discarded in the impact assessment as inappropriate for the sector. It would be detrimental to innovation and to the competitiveness of the European medical device sector, without any demonstrated added value for patient safety.

- A marketing authorisation, such as in the field of pharmaceuticals, would take at least 7 months (excluding stop the clock periods) compared to (on average) 3-6 months for the conformity assessment of a high-risk medical device under the current system. Moreover, while costs for market access for high-risk medical devices under the current legislation amount to (on average) 10,000€ - 30,000€, the costs for a marketing authorisation for a medicinal product amount to around 250,000 €.

- Therefore, a centralised marketing authorisation would have a significant impact in terms of time to market and costs for regulatory compliance. This would ultimately deprive patients of innovative medical devices and increase healthcare costs.

- A decentralised marketing authorisation would have in addition a negative impact on the internal market for medical devices since a Member State could refuse market access to a device authorised by another Member States because it considers that this device does not ensure an appropriate level of protection of health and safety.

1.4. What about provisions on manufacturers' liability and insurance?

- The proposal does not contain provisions on manufacturers' liability and insurance as there are already several general rules in place which also apply to producers of medical devices.

1.5. Do you expect agreements on Medical Devices before the next election of the European Parliament? Your predecessor sent a list of action points which the Council is hoping to implement regardless of whether new Regulations on Medical Devices and IVD Devices are completed. Is this an indication that the Commission and Council don't expect completion of the Medical Devices files?

- The MD and IVD proposals are urgently needed as they will change the current rules governing medical devices by reinforcing them in particular with regard to notified bodies, vigilance, market surveillance and transparency and by adapting them to the major technological progress achieved by this innovative sector since the 1990s.

- Their adoption under the current legislature is therefore a matter of priority for the Commission and is independent of the implementation of the (Poly Implant Prothèse) PIP action plan which is intended to respond on short term basis to the

PIP fraud on breast implants, due to the current limited provisions of medical devices legislative framework.

1.6. Why does the Commission propose that the future Regulation only become applicable 3 years after its adoption? And why a transitional period of 18 months is further necessary?

- The proposal introduces many changes in obligations for stakeholders in particular concerning reporting to the Eudamed database.

- Eudamed should be fully developed and operational, before requesting stakeholders to upload the information they should report.

- Furthermore **the transitional period** of 18 months is essential to ensure a smooth application of the registration of economic operators, devices and certificates would be only voluntary.

1.7. What is the Commission proposing on reprocessing of single use medical devices?

- Following the Commission report adopted on 27 August 2010, the proposal on medical devices introduces strict rules– balanced and based on the latest scientific knowledge - on such reprocessing of single-use devices. In particular:

  – Reprocessing of single-use devices is considered as manufacture of new devices, so that the re-processors must satisfy the obligations incumbent on manufacturers

  – Reprocessing of single-use devices for critical use (*e.g.* devices for surgically invasive procedures) is, as a general rule, prohibited.

  – Since certain Member States may have particular concerns in terms of safety regarding the reprocessing of single-use devices, the proposal foresees that they retain their right to maintain or impose a general ban on this practice.

1.8. What is the Commission's position on the classification in class III of certain devices composed of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body (Rule 21)?

- The new classification of these devices in class III addresses an important public health issue: some of these products, such as osmotic laxatives or fat absorbers, may be qualified as medical devices.

- However, they present some important risks that the current legislation does not address (such as interactions with medicinal products and toxicity) and no existing classification rule is adapted to these products.

- We should not wait to have an incident in order to put in place an appropriate risk classification of these products. We should keep in mind that they are used more and more often, on a chronic basis, sometimes by the elderly and without prescription or medical control.

- Without an appropriate risk classification of these products, the medical devices legislation will be transformed into a path to escape the costs and requirements of other legislations, in particular, food or medicines.

1.9. Isn't it better to enlarge the scope of the Medical Devices proposal to aesthetic devices through the introduction of a definition than through a positive list?

- The Commission proposal extends the scope of the legislation to cover certain implantable or other invasive products without medical purpose (*e.g.* dermal fillers, breast implants, contact lenses) by means of a positive list which is based on current experience on borderline products.

- The Commission considers that the positive list is the best approach. It would be difficult to draft a definition sufficiently precisely to capture the exact scope while avoiding creating grey areas. For example, "aesthetic" tattoos should not be appropriately regulated as medical devices and not covered by such definition while on the contrary 'aesthetic' liposuction equipment should be covered due to the risk they represent.

1.10. What is the Commission's position with regard to requirements on clinical investigations for medical devices

- Before adopting the Medical devices Package, the Commission had ensured where necessary, that alignment with the proposed provisions of the Commission proposal for a Regulation on clinical trials.

- The Commission calls on the co-legislators to keep, as much as possible, alignment with the proposal for a Regulation on clinical trials which is also currently in negotiation.

2. REVISION OF THE *IN VITRO* DIAGNOSTIC (IVD) MEDICAL DEVICE LEGISLATION

2.1. Are genetic tests sufficiently regulated?

- The proposal on *in vitro* diagnostic medical devices substantially reinforces the legal framework as regards designation, monitoring and functioning of Notified Bodies, risk classification, market surveillance, vigilance and transparency.

- It also substantially strengthens many aspects linked to genetic tests, in classifying all genetic tests in a high risk class, submitting all genetic tests to an assessment by a notified body, more detailed instructions for use and labelling, strengthened requirements on clinical evidence and regulation of devices used in the context of diagnostic services (*e.g.* services offered via the internet).

2.2. Why does to current derogation for Class D in-house tests need to be changed?

- The current Directive exempts so-called in house tests (*i.e.* tests manufactured and used within a single health institution) from the application of its requirements.

  The proposal foresees to keep this derogation for Class A, B and C while requiring that in for those classes, the single health institution manufacturing an using them

have a quality management system in place and is compliant with the EN ISO 15819 or equivalent standard.

- In order to appropriately address the obvious patient safety risks and to ensure a level playing field between single health institution and manufacturer, Class D in-house tests (e.g HIV tests) are proposed to be subjected to most of the requirements of the proposed Regulation.

- The Proposal foresees possibility for derogations, in the interest of public health and patient safety (e.g.Test to be developed for diagnose of emerging disease like Q fever)